REMARKS

The specification has been amended to correct typographical errors. Support for the amendment of the paragraph bridging pages 11 and 12 can be found at page 32, lines 17-20.

Claims 25 and 31 have been canceled.

Claims 24 and 30 have been amended to delete the superfluous phrase "of interest" and the term "Avr." Claims 24 and 30 have further been amended to specify that the DNA sequence encodes a protein comprising two domains that are an N-terminal resistance domain and a C-terminal inactive cell death domain. The N-terminal resistance domain is the resistance domain of Tav2b and the C-terminal inactive cell death domain is either an inactive cell death domain of Tav2b or the cell death domain of Cmv2b. Support for this language can be found in the claims as originally filed and throughout the specification.

Claim 32 has been amended to depend from claim 30 in view of the cancellation of claim 31 and to be consistent with the amended language of claim 30.

Claims 33, 35 and 36 have been amended to delete the multiple dependencies.

New Claims 38-43 have been amended to claim the subject matter previously set forth in the multiple dependencies of claims 33, 35 and 36 and dependent claims thereto.

It is submitted that none of the above amendments constitute new matter, and their entry is requested.

The Examiner has rejected claims 24-26 and 30-37 under U.S.C. § 112, second paragraph for being indefinite. It is submitted that the amendments to the claims obviate this rejection, since they no longer utilize the objected terms. Withdrawal of this rejection is requested.

The Examiner has rejected claims 24-26 and 30-37 under U.S.C. § 112, first paragraph for lack of written description. It is submitted that the specification provides a written description for the amended claims.

The amended claims are directed to a transgenic plant that has been transformed with a DNA sequence that encodes a protein comprising two domains. The two domains are an N-terminal

resistance domain and a C-terminal inactive cell death domain. The N-terminal resistance domain is the resistance domain of the Tav2b gene. The C-terminal inactive cell death domain is selected from the group consisting of an inactive cell death domain of the Tav2b gene and the cell death domain of the Cmv2b gene. The claims are no longer directed to any and all avirulence proteins that have an inactive cell death domain. They are now limited to an avirulence protein having the resistance domain of the Tav2b gene and an inactive cell death domain of either the Tav2b gene or the Cmv2b gene. The resistance domain of the Tav2b gene has been fully described in the specification. See for example, page 11, line 25 - page 12, line 1 and Examples 2 and 7-11. Similarly, the cell death domain of the Tav2b gene and the Cmv2b gene have been fully described in the specification. See for example, page 12, line 1 page 13, line 23 and Examples 7-11. In view of these descriptions in the specification, it is submitted that the specification reasonably conveys to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed.

In view of the above amendments and remarks, it is submitted that the claims comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Withdrawal of this rejection is requested.

The Examiner has rejected claims 24-26 and 30-37 under 35 U.S.C. § 112, first paragraph for lack of enablement. It is submitted that the specification fully enables the amended claims.

The Examiner has stated that the enablement issues are "the two-domain Avr gene under control of a promoter activated by infection with a plant pathogen, any pathogenic organism, and transgenic plants other than tomato and tobacco." With the exception of the citation of a 1988 reference (Agrios, G.N., *Plant Pathology*, 3rd Ed., Academic Press, San Diego, p. 43, 1988) in the first Office Action, the Examiner has not provided any scientific or technical reason to substantiate her contention that arriving at operable species of the invention would require excessive experimentation and an undue burden. However, Applicants submit that the Examiner has not set

forth an analysis of the *Wands* factors as required by the Patent Office's guidelines for enablement rejections. Thus, the Examiner has not presented a *prima facie* case of lack of enablement.

Furthermore, the "examiner has the initial burden to establish a reasonable basis to question the enablement provided for the **claimed** invention." MPEP2164.04; *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed.Cir.1993) (emphasis added). In *Wright*, the Court made clear that the PTO has the burden of providing a reasonable explanation of why the specification does not enable. Furthermore, there must be some reason to doubt the objective truth of the statements in the specification. M.P.E.P. § 2164.04; *In re Marzocchi*, 169 USPQ 367 (CCPA 1973). Applicants submit that the Examiner has not provided acceptable evidence to doubt the objective enablement of the specification and to support her contention that the specification is not enabling. As the Court said in *Marzocchi*,

> [I]t is incumbent upon the Patent Office, whenever a rejection on this basis [i.e. doubt of the objective truth of statements in the specification] is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go through the trouble and expense for supporting his presumptively accurate disclosure.

169 U.S.P.Q. at 370.

In addition, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known and already available to the public. M.P.E.P. § 2164.05(a). Applicants are not required to provide detailed information concerning matters which are known in the prior art and well within the ordinary skill of a practitioner. *See* M.P.E.P. § 2164.05(a).

Also, contentions, without scientific reasons or evidence are not sufficient to sustain an enablement rejection. *In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971). As provided in the M.P.E.P., if doubt arises about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without

undue experimentation, the examiner "should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation." M.P.E.P., 2164.04. Furthermore, while references may not be required for the Examiner to meet his or her burden, "specific technical reasons are **always** required. *Id.* (emphasis added) To determine enablement, the specification is considered in light of the knowledge in the art at the time of the invention. When considering the adequacy of enablement for a generic claim, the M.P.E.P. states that proof of enablement is required for other members of the genus "...only where **adequate reasons** are advanced by the Examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." M.P.E.P. at 2164.02.

As detailed above, the amended claims are directed to a specific protein and are not directed to any two-domain Avr gene. In addition, the specific protein comprises two domains, an N-terminal domain and a C-terminal domain, i.e., a linear relationship of the domains. Accordingly, the physical configuration of the constructs is established in the claims as described in the specification. That is, the two domains are in a linear arrangement and the DNA sequence encoding the protein is operatively linked to the promoter. Thus, these aspects of the enablement rejection are no longer applicable.

The promoter of claim 24 is a promoter capable of causing expression of the DNA sequence encoding the specified protein in the plant when the plant is infected with a pathogenic organism, i.e., a plant pathogen activated promoter. The promoter of claim 30 is any plant-active promoter. Certainly, the Examiner does not question the enablement of a plant-active promoter, since there are many that were known in the prior art prior to the filing date of the present application. Similarly, plant pathogen activated promoters were well known to skilled artisans prior to the filing date of the present application and were shown to be useful in different plant species. Such promoters include promoters of pathogen-related proteins. This knowledge is shown by the attached copies of abstracts. These abstracts are not intended to be exhaustive, but are merely representative of knowledge in the art at the time of the filing of the application.

Beilmann, A. et al. (1992). "Activation of a truncated PR-1 promoter by endogenous enhancers in transgenic plants." *Plant Mol Biol* **18**:65-78.

Eyal, Y. et al. (1993). "A basic-type PR-1 promoter directs ethylene responsiveness, vascular and abscission zone-specific expressoin." *Plant J* **4**:225-34.

Henning, J. et al. (1993). "Pathogen, salicylic acid and developmental dependent expression of a beta-1,3-glucanase/GUS gene fusion in transgenic tobacco plants." *Plant J* **4**:481-93.

Shah, J. and Klessig, D.F. (1996). "Identification of a salicylic acid-responsive element in the promoter of the tobacco pathogenesis-related beta-1,3-glucanase gene, PR-2d." *Plant J* **10**:1089-101.

Shah, J. et al. (1997). "Characterization of a salicylic acid-insensitive mutant (sai1) of Arabidopsis thaliana, identified in a selective screen utilizing the SA-inducible expression of the tms2 gene." *Mol Plant Microbe Interact* **10**:69-78.

Tornero, P. et al. (1997). "Two PR-1 genes from tomato are differentially regulated and reveal a novel mode of expression for a pathogenesis-related gene during the hypersensitive response and development." *Mol Plant Microbe Interact* **10**:624-34.

Warner, S.A. et al. (1993). "Isolation of an asparagus intracellular PR gene (AoPR1) wound-responsive promoter by the inverse polymerase chain reaction and its characterization in transgenic tobacco." *Plant J* **3**:191-201.

Thus, Applicant submits that plant pathogen activated promoters and their use were well known to a skilled artisan at the time of filing of the application. In addition, the Examiner has not cited any scientific or technical reasons to support her contentions concerning plant pathogen activated promoters nor to doubt the objective enablement of the specification. The Examiner has not provided any specific technical reasons to demonstrate that **undue** experimentation would be required to practice the claimed subject matter. Consequently, it is submitted that the specification fully enables plant pathogen activated promoters and plant-active promoters.

Systemic acquired resistance (SAR) was well known in the art prior to the filing date of the present invention. It was known that SAR was a non-specific defense response in plants that when activated protects plants from infection by a wide variety of pathogens. It was known that this response could be activated by biological inducers, i.e., plant pathogens, and by chemical inducers,

e.g., salicylic acid. This knowledge is shown by the attached copies of literature papers. These papers are not intended to be exhaustive, but are merely representative of knowledge in the art at the time of the filing of the application.

Bowling, S.A. et al. (1994). "A mutation in Arabidopsis that leads to constitutive expression of systemic acquired resistance." *Plant Cell* **6**:1845-57.

Ryals, J.A. et al. (1996). "Systemic Acquired Resistance." *Plant Cell* **8**:1809-1819.

Thus, Applicant submits that the ability of SAR to protect a plant from many different plant pathogens was well known to a skilled artisan at the time of filing of the application. In addition, the Examiner has not cited any scientific or technical reasons to support her contentions concerning any pathogenic organism nor to doubt the objective enablement of the specification. The Examiner has not provided any specific technical reasons to demonstrate that **undue** experimentation would be required to practice the claimed subject matter. Consequently, it is submitted that the specification fully enables "any pathogenic organism."

Applicants have shown the invention functions in three different plant species in two different genera, beyond tomato in which it was known that the Tav2b gene is active. Specifically, Applicants have shown activity in *Nicotiana xanthum*, *X. benthamiana* and *Physalis floridana*. Thus, activity in three different genera has been established. In addition, the activity of a plant pathogen activated promoter in a fourth genera is shown by the Shah et al. (1997) abstract cited above, and the applicability of SAR to many different genera is shown by the Ryals et al. (1996) paper cited above. Furthermore, the Examiner has not cited any scientific or technical reasons to support her contentions concerning any transgenic plant other than tobacco and tomato nor to doubt the objective enablement of the specification. The Examiner has not provided any specific technical reasons to demonstrate that **undue** experimentation would be required to practice the claimed subject matter. Consequently, it is submitted that the specification fully enables "any transgenic plant."

In view of the above amendments and remarks, it is submitted that the specification fully enables the claimed subject matter in accordance with the requirement of 35 U.S.C. § 112, first paragraph. Withdrawal of this rejection is requested.

In view of the above amendments and remarks, it is submitted that the claims satisfy the requirements of the patent statutes and are patentable over the prior art. Reconsideration of the instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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